UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 18-10568-RGS

DUSA PHARMACEUTICALS, INC.

v.

BIOFRONTERA INC., BIOFRONTERA BIOSCIENCE GMBH, BIOFRONTERA PHARMA GMBH, and BIOFRONTERA AG

MEMORANDUM AND ORDER ON
CROSS-MOTIONS FOR SUMMARY JUDGMENT
ON PATENT CLAIMS

October 9, 2020

STEARNS, D.J.

Plaintiff DUSA Pharmaceuticals, Inc., accuses defendants Biofrontera Inc., Biofrontera Bioscience GMBH, Biofrontera Pharma GMBH, and Biofrontera AG (collectively Biofrontera) of patent infringement and trade secret misappropriation.[1] Discovery having been completed, the parties exchange salvos in the form of six motions to strike expert testimony and

[1] DUSA's Second Amended Complaint (dkt # 84) sets out seven claims: patent infringement (Counts I & II); trade secret misappropriation under the Defend Trade Secrets Act (Count III); trade secret misappropriation under Mass. Gen. Laws ch. 93, § 42 (Count IV); common-law misappropriation of confidential, proprietary, and trade secret information (Count V); tortious interference with contractual relations (Count VI); and deceptive and unfair trade practices under Mass. Gen. Laws ch. 93A (Count VII).

three motions for summary judgment. This memorandum addresses the cross-motions for summary judgment on DUSA's patent claims.

BACKGROUND

DUSA asserts two patents – U.S. Patents Nos. 8,216,289 (the '289 patent) and 9,723,991 (the '991 patent). The '289 and the '991 patents are both entitled "Illuminator for Photodynamic Therapy" and share a specification.

> In PDT [(photodynamic therapy)], a patient is administered a photoactivatable agent or precursor of a photoactivatable agent which accumulates in the tissue being diagnosed or treated. An area of the patient which includes the tissue being diagnosed or treated is then exposed to visible light. The visible light causes chemical and/or biological changes in the photoactivatable agent which in turn selectively locate, destroy or alter the target tissue while at the same time causing only mild and reversible damage to other tissues in the treatment area.

'289 patent, col. 1, ll. 41-50. The '289 and '991 patents are directed to improvements in PDT, including the output of "visible light of consistent uniformity in terms of both spectral characteristics and intensity over a diversely contoured surface." *See id.*, col. 2, ll. 45-47. Claim 1 of each patent is representative.

> '991 patent claim 1. An illuminator for diagnosing or treating a patient, comprising:
>
> a plurality of light sources configurable in a spaced relationship to a patient to treat or diagnose a dermatological condition,

> a controller, connected to the plurality of light sources, to control the light sources,
>
> wherein the light sources are configured and controlled to provide a uniform output of light to the patient to treat or diagnose a dermatological condition,
>
> the light sources being configured and controlled such that uniform output of light is provided when measured at distances of 2'' and 4''.

'289 patent claim 1. A method of photodynamically diagnosing or treating a patient, comprising:

> illuminating the patient with an illuminator whose measured output over an active emitting area is at least 60% of the measured maximum over all operation distances.

In March of 2019, the court construed the disputed claim terms. *See DUSA Pharm., Inc. v. Biofrontera Inc.*, 2019 WL 1208805 (D. Mass. Mar. 14, 2019). Of relevance here, the court agreed with DUSA that the claimed "illuminator" was not limited to a specific shape. *Id.* at *4-7. Although the patents largely described a contoured illuminator, the evidence fell short of the exacting standard for finding the disavowal of a flat illuminator. *Id.*

Since 2000, DUSA has offered for sale a BLU-U PDT light, and Levulan, a photosensitizer drug. The combined therapy is approved by the Federal Food and Drug Administration (FDA) for the treatment of actinic

keratosis.[2] Biofrontera began, in October of 2016, selling a competing PDT light, the accused BF-RhodoLED, with a photosensitizing drug called Ameluz. Biofrontera's products are also FDA-approved for treating actinic keratosis.

BIOFRONTERA'S MOTION

In defendants' quiver there are three arrows. First, Biofrontera asserts that DUSA's patents are invalid for inadequate written description – the claims, in DUSA's view, cover a flat illuminator, but such an embodiment is absent from the specification. Second, Biofrontera characterizes the asserted claims as being directed to the desired result of *uniform light* and are therefore patent-ineligible under 35 U.S.C. § 101. Finally, Biofrontera contends that DUSA is not entitled to lost profits because its evidence cannot establish that it would have captured Biofrontera's sales "but for" the alleged infringement.

Written Description

The patent laws require a "specification [to] contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person

[2] Actinic keratoses are precancerous skin lesions caused by chronic sun exposure that can develop over time into a form of skin cancer called squamous cell carcinoma.

skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112 ¶ 1. "[T]he purpose of the written description requirement is to 'ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification.'" *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1353-1354 (Fed. Cir. 2010) (citation omitted). "Written description is a question of fact" that "depends on 'the nature and scope of the claims and on the complexity and predictability of the relevant technology.'" *Tobinick v. Olmarker*, 753 F.3d 1220, 1226 (Fed. Cir. 2014) (citation omitted). "[T]he test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharm*, 598 F.3d at 1351. "Possession" is measured by "an objective inquiry into the four corners of the specification." *Id.*

As Biofrontera sees it, the patents do not support the full scope of the claims as construed – that is, an illuminator that produces the claimed uniform light without any limitation to shape. The patents describe and trumpet the benefit of a contoured embodiment. *See, e.g.*, '289 patent, Fig. 1; col. 6, ll. 31-42 ("The U-shape minimizes the variations in distance

between the emitter and the target, providing a uniform visible light distribution to the face or scalp of the patient; the tube dimensions were chosen based on the average dimensions of the adult human head. . . . Moreover, the 'U' shape provides the desired irradiance and irradiance uniformity for Scalp and facial irradiation, and thus ensures that the proper visible light dosage is applied to all target areas during PDT."). By way of contrast, there is no disclosure of a flat embodiment, and the only mention[3] of a flat illuminator is in disparagement: "A flat emitting surface would not deliver a uniform light dose to all contours of the face simultaneously because the non-planar facial and scalp surfaces could not be placed at a constant distance from the emitting surface." '289 patent, col. 4, ll. 35-39. A person of skill in the art, therefore, would not understand that the patentee had invented a flat illuminator capable of emitting the claimed uniform light.[4]

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[3] Biofrontera also maintains that a person of ordinary skill in the art would not understand the patents' description of an "infinite plane emitter," *see* '289 patent, col. 3, ll. 36-44, to disclose a flat embodiment, as DUSA's technical expert agrees that "an infinite plane emitter is a theoretical concept." Defs.' Ex. 5, Zamenhof Dep. Tr. (dkt # 257-5) at 178:3-7.

[4] In Biofrontera's analysis, the claims directed to uniform light are akin to

> genus claims that use functional language to define the boundaries of a claimed genus. In such a case, the functional

DUSA, for its part, points out that the written description provision does not require that the specification "describe . . . every conceivable and possible future embodiment of [the] invention," *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1365 (Fed. Cir. 2003) (citation omitted); nor must "every claim [] contain every limitation or achieve every disclosed purpose," *ScriptPro LLC v. Innovation Assocs., Inc.*, 833 F.3d 1336, 1342 (Fed. Cir. 2016). Where, as here, the shape of an illuminator is not a claimed element, "[t]here is no requirement that a patent describe the unclaimed features of the infringing product." *Hologic, Inc. v. Minerva Surgical, Inc.*, 325 F. Supp. 3d 507, 526 (D. Del. 2018). In the same vein, DUSA characterizes the cases discussing written description as focused on the "patentee's failure to disclose specifically claimed features." Opp'n (dkt # 288) at 5-6, citing *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997); *Rivera v. Int'l Trade Comm'n*, 857 F.3d 1315, 1317-1318, 1319-1320 (Fed. Cir. 2017); *Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1563, 1567-1568

> claim may simply claim a desired result, and may do so without describing species that achieve that result. But the specification must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus.

Ariad, 598 F.3d at 1349.

(Fed. Cir. 1997); *Atl. Research Mktg. Sys., Inc. v. Troy*, 711 F. Supp. 2d 218, 221-222 (D. Mass. 2010).

While the nondisclosure of a claimed feature may offend section 112 ¶ 1, so too could "a broadly drafted claim [not] fully supported by the written description and drawings." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1333 (Fed. Cir. 2003). In *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336 (Fed. Cir. 2005), the Court invalidated a claim directed to creating a seamless array of discrete wave transformation (DWT) coefficients generically, where the specification had only described one particular method for creating a seamless DWT. *Id.* at 1345. "Whether the flaw in the specification is regarded as a failure to demonstrate that the patentee possessed the full scope of the invention recited in claim 21 or a failure to enable the full breadth of that claim, the specification provides inadequate support for the claim under section 112, paragraph one." *Id.*

Similarly, in *Tronzo v. Biomet, Inc.*, 156 F.3d 1154 (Fed. Cir. 1998), the Court invalidated claims directed to an artificial hip-implant socket without any limitation as to its shape. *Id.* at 1159-1160. In *Tronzo*, the specification described a conical shaped cup and referenced other shapes only in the context of describing and distinguishing prior art. *Id.* at 1159. The Court

held that the "narrow language" of the specification did not support the full scope of the claims. *See id.* at 1159-1160.

The court agrees with Biofrontera in the first instance that the asserted claims may well be vulnerable under *LizardTech* and *Tronzo* in light of their broad sweep. Specifically, claim 1 of the '289 patent is directed to a method of PDT using an illuminator capable of achieving the desired output uniformity without any other limitation on the illuminator. That said, the court agrees with DUSA that the evidence presents a "genuine dispute [of] material fact" as to whether the patents adequately disclose a non-contoured illuminator. Fed. R. Civ. P. 56(a). The patents' disclosure of an infinite plane emitter is consistent with a flat illuminator. *See* '289 patent, col. 3, ll. 36-44. Independent of shape, the patents disclose other improvements to an illuminator such as a cooling system and a controller. *See* '289 patent, col. 9, ll. 5-46; col. 10, ll. 53 - col. 11, l. 6. The disparagement of a flat illuminator is specific to the context of applying PDT to a human face, a highly contoured surface, *see id.* col. 4, ll. 35-39, while the patents contemplate treatment of other less contoured aspects of a human body; *see id.* col. 1, ll. 26-29. Indeed, claim 1 of the '991 patent recites a controller, and is not limited to treatment

of the human face.[5] Taken ensemble, and drawing all reasonable inferences in favor of DUSA as the non-moving party, the court cannot as a matter of law rule that the patentee, from the perspective of a person skilled in the art, did not "possess" a flat illuminator capable of achieving the desired light uniformity.

Subject Matter Eligibility

While "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" are patentable, 35 U.S.C. § 101, "'laws of nature, natural phenomena, and abstract ideas' are not patentable." *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 70 (2012), quoting *Diamond v. Diehr*, 450 U.S. 175, 185 (1981). In evaluating subject matter eligibility,

> [f]irst, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. [*Mayo*], 566 U.S. at 77-78. If so, we then ask, "[w]hat else is there in the claims before us?" *Id.*, at 78. To answer that question, we consider the elements of each claim both individually and "as an ordered combination" to determine whether the additional elements "transform the nature of the claim" into a patent-eligible application. *Id.*, at 79, 78. We have described step two of this analysis as a search for an "'inventive concept'" – *i.e.*, an element or combination of elements that is "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself." *Id.*, at 72-73.

[5] In contrast, claim 10 of the '991 patent, a dependent claim, is limited by the following qualification – "wherein the plurality of light sources are configured to illuminate the face of the patient."

Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. 208, 217-218 (2014).

In a reprisal and expansion of its claim of an inadequate written description, Biofrontera maintains that DUSA's claims are patent-ineligible under section 101. As Biofrontera frames the argument, because the first step of claim 1 of the '289 patent contains no limitation as to how the desired uniform light is produced, it in effect claims the characteristics of light itself, and is thus directed to an unpatentable natural phenomenon. Biofrontera analogizes the recitation of an unspecified illuminator to the invocation of a black box computer that the Supreme Court has held incapable of transforming an unpatentable idea into a protectible invention. *See Alice*, 573 U.S. at 223-224. Biofrontera also accuses claim 1 of the '991 patent of the same transgression – in its view, the claimed "a plurality of light sources configurable in a spaced relationship to a patient" and "controller" are "generic components." Reply (dkt # 316) at 10.

At step two, Biofrontera notes that while the patents explain that "[t]he present invention differs from conventional light sources because of the biological requirements imposed on a PDT light source[, and a] much higher degree of precision and integration is required for the components of the present invention," '289 patent, col. 4, ll. 18-22, these touted improvements

are not incorporated in the claims. Biofrontera therefore concludes that the claims lack an inventive concept.

DUSA maintains, and the court agrees, that the claims are directed to an illuminator and a method for using the illuminator in PDT. Although the claims relate to light, they are not directed to light as a *natural* phenomenon. The uniformity of light output is a requirement of and inseparable from the claimed illuminator. Claim 1 of the '981 patent requires that "the light sources are configured and controlled to provide a uniform output of light to the patient to treat or diagnose a dermatological condition," and that "uniform output of light is provided when measured at distances of 2" and 4"." The court construed "uniform output of light" as "the measured irradiance of light over the active emitting area [that] is at least within 60% of the measured maximum." Claim 1 of the '289 patent explicitly requires "an illuminator whose measured output over an active emitting area [that] is at least 60% of the measured maximum over all operation distance."[6] That the uniformity of the light output is measured in relation to "an active emitting area" additionally confirms that light, in the context of the claims, is a product of the claimed illuminator.

[6] The court construed "all operation distances" as "the range of distances between 2" and 4"."

On this point, *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013) (*Myriad*) is instructive. In *Myriad*, the Supreme Court held that claims directed to the sequence of two genes known to predispose an individual to breast cancer were not patentable. "It is undisputed that Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them. Nor did Myriad create or alter the genetic structure of DNA." *Id.* at 590. By contrast, the Court ruled that synthesized exons-only cDNA – created from naturally occurring sequences of mRNA but with the non-coding introns removed – was patent-eligible (with the exception of very short DNA sequences without introns). "[T]he lab technician unquestionably creates something new when cDNA is made. cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived. As a result, cDNA is not a 'product of nature' and is patent eligible under § 101." *Id.* at 595.

Here, Biofrontera identifies no evidence that the light at issue here – whose measured irradiance over the active emitting area is at least within 60% of the measured maximum from 2" to 4" – is a naturally occurring phenomenon or the known product of conventional illuminators. The '289 patent explains that the "[o]utput spectrum, irradiance, and irradiance

uniformity all must be controlled to assure that the properties of the device are suitable to deliver light to the target lesions and drive the photodynamic reaction." '289 patent, col. 4, ll. 22-25. Like the cDNA in *Myriad*, the light output of the asserted claims is created – in this case, by illuminators engineered to produce the specified uniformity. Accordingly, the claimed illuminator and method to use the illuminator to perform PDT do not fall within the patent-ineligible category of natural phenomena.

Lost Profits

To recover lost profits, a patentee must "show 'causation in fact,' establishing that 'but for' the infringement, [it] would have made additional profits." *Grain Processing Corp. v. Am. Maize-Prod. Co.*, 185 F.3d 1341, 1349 (Fed. Cir. 1999). DUSA presents its lost profits analysis under the so-named *Panduit* factors. *See Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1156 (6th Cir. 1978); *see also Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1284 (Fed. Cir. 2017) ("One 'useful, but non-exclusive' method to establish the patentee's entitlement to lost profits is the Panduit test first articulated by the Sixth Circuit."). Under the *Panduit* test, a patentee is entitled to lost profits if it demonstrates:

(1) demand for the patented product;

(2) absence of acceptable non-infringing alternatives;

> (3) manufacturing and marketing capability to exploit the demand; and
>
> (4) the amount of profit it would have made.

Mentor Graphics, 851 F.3d at 1285, citing *Panduit*, 575 F.2d at 1156.

Biofrontera brings dual challenges to DUSA's assertion of the absence of acceptable non-infringing alternatives. First, DUSA's damages expert witness, Dr. Jeffrey Stec, does not consider other light sources – such as sunlight, Omnilux, Akilite, and lasers – as acceptable non-infringing alternatives because they are not FDA-approved for PDT. Biofrontera maintains that FDA approval is not related to the Asserted Patents, nor is it a patented feature. *Cf. Standard Havens Prod., Inc. v. Gencor Indus., Inc.*, 953 F.2d 1360, 1373 (Fed. Cir. 1991) ("[I]f purchasers are motivated to purchase because of particular features available only from the patented product, products without such features – even if otherwise competing in the marketplace – would not be acceptable noninfringing substitutes."). Biofrontera also points to evidence that physicians in fact use these non-FDA-approved light sources in PDT, *see* Biofrontera's Statement of Undisputed Material Facts (SUMF, dkt # 254) ¶¶ 60-62, thus fortifying its position that they are acceptable non-infringing alternatives.

At this summary judgment stage, the court agrees with DUSA that a reasonable factfinder could conclude that a PDT light source – a device used

in medical treatment – is not an acceptable non-infringement alternative if it does not have FDA approval. *See Datascope Corp. v. SMEC, Inc.*, 879 F.2d 820, 825 (Fed. Cir. 1989) (alleged competing percutaneous intra-aortic balloon catheter did not constitute a non-infringing alternative because, *inter alia*, it did not have FDA approval). To underscore this point, DUSA notes that Biofrontera's CEO, Hermann Luebbert, does not consider companies selling PDT lamps without FDA approval to be legitimate market competitors. *See* DUSA's Statement of Additional Material Facts (SAMF, dkt # 292) ¶ 18. Biofrontera's counsel and numerous Biofrontera witnesses have also repeatedly declared the PDT market to be a "two-player[]" market, meaning DUSA and Biofrontera. DUSA SAMF ¶ 16.

Second, Biofrontera suggests that non-PDT treatments for actinic keratosis – such as cryotherapy, prescription topicals, and surgical removal or curettage – are effective acceptable non-infringing alternatives. Although these treatments lack "uniform light," Biofrontera asserts that DUSA has no evidence that "uniform light" drives demand for the patented PDT. Biofrontera notes that in the three years before it entered the PDT market, 20% of DUSA's customer accounts stopped placing orders with DUSA, while 30% of the DUSA accounts decreased significantly in volume. Biofrontera SUMF ¶ 123. Between 2015 and 2017, DUSA lost 7% of its market share,

while Biofrontera only gained 1%. *Id.* ¶ 129. Biofontera's suggestion is that even in the absence of its competition, physicians chose non-PDT treatments as alternatives to DUSA's products.

The court however agrees with DUSA that it has adduced sufficient evidence, that if credited, would permit a reasonable factfinder to conclude that these non-PDT treatments do not constitute non-infringement alternatives for purposes of the causation analysis. "Mere existence of a competing device does not make that device an acceptable substitute." *TWM Mfg. Co. v. Dura Corp.*, 789 F.2d 895, 901 (Fed. Cir. 1986). "A product lacking the advantages of that patented can hardly be termed a substitute 'acceptable' to the customer who wants those advantages." *Id.*, quoting *Panduit*, 575 F.2d at 1162. Here, PDT is a non-invasive procedure that typically achieves superior cosmetic results for the patient. DUSA SAMF ¶¶ 25-26. In contrast, cryotherapy carries side effects such as pain and blistering, and the loss of skin pigmentations. *Id.* ¶¶ 19-24. Topical treatments require a much longer treatment period in addition to possible inflammation, redness, pain, and itching. *Id.* ¶¶ 27-31. Destructive therapies like surgery and curettage, in addition to being invasive and potentially requiring sedation, have not been evaluated in clinical trials. *Id.* ¶ 32. Further, a reasonable factfinder could agree with DUSA's expert witness, Dr.

Stec, that for purposes of the "but for" analysis, because they chose PTD, the purchasers of Biofrontera's accused products would not have opted for a non-PTD treatment.

In addition to its arguments directed to the second *Panduit* factor, Biofrontera contends that in the hypothetical absence of its competing products from the market, DUSA would not have captured Biofrontera's sales because of significant differences between the two products. "To be acceptable to the infringer's customers in an elastic market, the alleged alternative 'must not have a disparately higher price than or possess characteristics significantly different from the patented product.'" *BIC Leisure Prod., Inc. v. Windsurfing Int'l, Inc.*, 1 F.3d 1214, 1219 (Fed. Cir. 1993). Biofrontera notes that its BF-RhodoLED costs $6,700, compared to $7,500 for the BLU-U, and that its Ameluz was similarly more affordable at $270, compared to DUSA's Levulan at $380. Biofrontera also points to evidence that DUSA had lost sales as a result of repeated price increases in the several years prior to Biofrontera's entry into the market, *see* Biofrontera SUMF ¶¶ 123-127, and that customers preferred the BF-RhodoLED for its red light (compared to BLU-U's blue light), *see id.* ¶¶ 95-96.

In response, DUSA cites evidence that despite price increases, sales for BLU-U and Levulan increased between 2015 and 2016 before experiencing a

substantial decline after Biofrontera entered the market. *See* DUSA SAMF ¶ 38. Further, because physicians are reimbursed in full for the out-of-pocket expenses of PDT, the cost difference between PDT products is not a material factor in most physician purchasing decisions. *See id.* ¶ 35. Finally, DUSA notes that "[t]he patentee is not obligated to negate every possibility that a purchaser might not have bought the patentee's product instead of the infringing one, or might have foregone the purchase altogether." *Datascope*, 879 F.2d at 826, quoting *Del Mar Avionics, Inc. v. Quinton Instrument Co.*, 836 F.2d 1320, 1326 (Fed. Cir. 1987). Rather, the proper focus of the *Panduit* analysis is not to compare the patentee's product to the accused product, but instead to acceptable non-infringing alternatives. *See Grain Processing*, 185 F.3d at 1351. Taken together, particularly with Biofrontera's acknowledgement of a "two-player" PTD market, the court agrees with DUSA that "but for" causation is a matter to be decided (contingent on a finding of infringement) by the finder of fact.

DUSA'S MOTION

DUSA returns fire with two volleys of its own. First, DUSA asserts that the Paterson Lamp, cited in Biofrontera's invalidity arguments, does not qualify as anticipatory prior art to the asserted DUSA patents. Second, DUSA

seeks partial summary judgment that certain claim limitations are met by the accused BF-RhodoLED because they are uncontested by Biofrontera.

The Paterson Lamp

DUSA asserts a priority date of May 1, 1998 for its patents.[7] DUSA's SUMF (dkt # 270) ¶ 3. To qualify as prior art under 35 U.S.C § 102(a), a device must have been "known or used by others in this country" prior to the invention claimed by the asserted patents.[8] As Biofrontera describes it, the Paterson Lamp was "developed by Colin Whitehurst, among others, at the Paterson Institute [for Cancer Research] in the early-to-mid 1990's,"[9] and "was used in photodynamic therapy tests and treatments by Dr. Whitehurst, Dr. [Colin] Morton, and Dr. [Harry] Moseley, among others, in the mid-1990's." Biofrontera's SAMF (dkt # 286) ¶ 4. There is admittedly no evidence that the Paterson Lamp was ever sold, used, or demonstrated in the United States. Biofrontera contends, however, that through five articles

[7] This is the filing date of the earliest parent application identified by each patent.

[8] Biofrontera has withdrawn the assertion of the Paterson Lamp as prior art under section 102(b), which requires an apparatus, *inter alia*, to be "in public use or on sale in this country." Biofrontera's Opp'n (dkt # 285) at 5 n. 3.

[9] The Paterson Institute is located in the United Kingdom.

published in the United States, the Paterson Lamp was "known . . . in this country." The articles are:

- "Development of Alternative Light Source to Lasers for Photodynamic Therapy: 1. Comparative In Vitro Dose Response Characteristic" (Whitehurst 1993), published Lasers in Medical Science in 1993, *id.* ¶ 5;

- "Development of Alternative Light Source to Lasers for Photodynamic Therapy: 2. Comparative In Vivo Tumour Response Characteristics" (Whitehurst 1995), published in Lasers in Medical Science in 1995, *id.* ¶ 7;

- "Development of Alternative Light Source to Lasers for Photodynamic Therapy: 3. Clinical Evaluation in the Treatment of Pre-malignant Non-melanoma Skin Cancer" (Morton), published in Lasers in Medical Science in 1995, *id.* ¶ 9;

- "Development of an Alternative Light Source to Lasers for Biomedical Applications" (Whitehurst 1996), published in the Proceedings of SPIE 2629, Biomedical Optoelectronics in Clinical Chemistry and Biotechnology, on January 8, 1996, *id.* ¶ 12; and

- "Performance of a Nonlaser Light Source for Photodynamic Therapy" (SPIE2371), published in the Proceedings of SPIE 2371, 5th International Photodynamic Association Biennial Meeting, on March 1, 1995, *id.* ¶ 14.

In DUSA's view, because each of the five articles discloses a different iteration of a prototype device with significantly different features, they do not identify the Paterson Lamp as a monolithic prior art device melding features from across the iterations.[10] *See Studiengesellschaft Kohle, m.b.H.*

[10] DUSA's motion neither challenges the status of the articles themselves as prior art references, nor Biofrontera's obviousness

v. Dart Indus., Inc., 726 F.2d 724, 726-727 (Fed. Cir. 1984) ("It is hornbook law that anticipation must be found in a single reference, device, or process."); *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1335 (Fed. Cir. 2002) ("Although we have permitted the use of additional references to confirm the contents of the allegedly anticipating reference, we have made clear that anticipation does not permit an additional reference to supply a missing claim limitation.") (citation omitted). As DUSA analyzes it, the iterations of the Paterson Lamp in the five articles possess varying treatment field sizes, dimensions, attachments, power output, and treatment subjects. *See* DUSA's SUMF ¶¶ 19-27; *see also id* ¶ 28 (reflecting the different device photographs/illustrations of the articles). Indeed, Biofrontera's invalidity expert witness, Dr. Irving Bigio, agrees that there was "more than one version of [the Paterson Lamp.]" DUSA Ex. 6, Bigio Dep. Tr. (dkt # 269-6) at 241:14-19. Further, DUSA notes that the none of the articles disclose the distance at which uniform measurements were taken, a key limitation for the asserted claims. According to DUSA, Biofrontera relies on Dr. Moseley's testimony for this information, and Dr. Moseley's present-day testimony does not constitute public knowledge at the time of invention for purposes of § 102.

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contentions based on the combination of the articles. *See* DUSA's Br. (dkt # 268) at 3 n.3.

Biofrontera maintains, and the court agrees, that there is sufficient evidence, if credited, to permit a factfinder to consider the Peterson Lamp as a prior art device. DUSA's expert witness, Dr. Robert Zamenhof, acknowledges that the five articles reflect the development and use of a lamp by the same group of individuals who authored the articles. *See* Biofrontera's Ex. 5, Zamenhof Dep. Tr. (dkt # 287-5) at 72:20-74:3. While the characteristics of the Paterson Lamp "change[d] somewhat" throughout the articles, the articles describe "the development of the *same* lamp," and "a person of ordinary skill would look to these articles together to understand the full development of the [] Lamp." *Id.* at 76:10-20 (emphasis added).

The record also supports the reasonable inference that the differences between the iterations of the Paterson Lamp are not material for the anticipation analysis. In *In re Epstein*, 32 F.3d 1559 (Fed. Cir. 1994), the Federal Circuit accepted the PTO's reliance on later-authored manuals and abstracts for descriptions of the "central" features in versions of prior art software as a basis for rejecting a patent application. *Id.* at 1567.

> [W]e are persuaded by the relative importance of the various prior art features upon which the PTO relies when those features are considered in the context of the prior art products in which they appear. After reviewing the abstracts and the examiner's positions in this case, it appears to us that the features relied upon are not of the type that would be altered over the life of the product, either to upgrade the system or to eliminate existing bugs in the system. To the contrary, the relatively broad features

> relied upon by the examiner relate to the central purposes of the systems in which the features appear.

Id. Here, the five published articles consistently disclosed what Biofrontera contends are the "central" features of the Paterson Lamp – that it boasted a high-powered short arc lamp with collimated fibers/lenses to create uniform light output. *See* Biofrontera Ex. 10, Bigio Report (dkt # 287-10) ¶¶ 195-205. Indeed, these are the same features Dr. Bigio relied upon in his invalidity analysis. *See id.* In contrast, Dr. Bigio's report does not align any of the variable features identified by DUSA with any claim limitation. *See id.*, generally. Finally, Dr. Bigio opines that to the extent that the articles do not explicitly disclose the distance at which uniformity of light is measured, it is inherent in the use of a collimating lens and the uniformity statistics reported by the articles.[11] *Id.* ¶ 207. In sum, considering the totality of the evidence and drawing all reasonable inferences in favor of Biofrontera as the non-moving party, a factfinder could conclude that the five articles sufficiently described that "central" features of the Paterson Lamp such that it was "known in the [United States]."

[11] As DUSA implicitly acknowledges in its reply, whether the Paterson Lamp discloses every claimed limitation is an issue for anticipation analysis, and is not instructive on the issue of whether the five articles sufficiently evidence the Paterson Lamp as a single prior art device. *See* DUSA Reply (dkt # 308) at 5-6.

Uncontested Claim Limitations

DUSA seeks partial summary judgement on the following limitations of the asserted patents.

- the BF-RhodoLED is used to "photodynamically [] treat[] a patient" ('289 patent, all claims);
- the BF-RhodoLED is used to "illuminat[e] a patient with an illuminator" ('289 patent, all claims);
- "the spectral output of [the BF-RhodoLED] substantially matches the absorption spectrum of protoporphyrin IX" ('289 patent, claim 4);
- the BF-RhodoLED is used "to treat actinic keratosis" ('289 patent, claim 7), "acne" ('289 patent, claim 8), "photo damaged skin" ('289 patent, claim 9), "cancer" ('289 patent, claim 10), "warts" ('289 patent, claim 11), and "a pre-cancerous condition" ('289 patent, claim 15).
- the BF-RhodoLED is "[a]n illuminator for [] treating a patient" ('991 patent, all claims);
- the BF-RhodoLED contains "a plurality of light sources configurable in a spaced relationship to a patient to treat a dermatological condition" ('991 patent, all claims);
- "the spectral output of the [BF-RhodoLED] substantially matches an absorption spectrum of protoporphyrin IX" ('991 patent, claim 5);

- the BF-RhodoLED "generates light substantially entirely within the red region" ('991 patent, claim 7);
- "the light sources [of the BF-RhodoLED] are non-fluorescent light sources" ('991 patent, claim 9);
- "the plurality of light sources [of the BF-RhodoLED can be] configured to illuminate the face of the patient ('991 patent, claim 10); and
- the BF-RhodoLED provides "red light to the patient to treat [] a dermatological condition" ('991 patent, claim 12).

In support, DUSA relies on the report of its technical expert witness, Dr. Zamenhof, the testimony of Biofrontera's witnesses, and exhibits such as the user manual for the BF-RhodoLED, Biofrontera's FDA submissions, and Biofrontera's Responses to Requests for Admissions. *See* DUSA's SUMF ¶¶ 32-48. DUSA further notes that Biofrontera's technical expert witness, Bryan Spring, does not contest these limitations in his rebuttal expert report.

Biofrontera challenges the propriety of summary judgment on claim limitations rather than claims, noting that the claims themselves will nonetheless have to be tried before the factfinder. The Civil Rules, however, permit summary judgment on "part of each claim," Fed. R. Civ. P 56(a), and the court agrees with DUSA that reducing the number of disputed issues will aid in streamlining the factfinding process.

Biofrontera for its part challenges the sufficiency of the evidence as to the asserted method claims. "To establish liability for direct infringement of a claimed method or process under 35 U.S.C. § 271(a), a patentee must prove that each and every step of the method or process was performed." *Aristocrat Techs. Australia Pty Ltd. v. Int'l Game Tech.*, 709 F.3d 1348, 1362 (Fed. Cir. 2013). "[I]t is not enough to simply show that a product is capable of infringement; the patent owner must show evidence of specific instances of direct infringement." *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1329 (Fed. Cir. 2010).

For most of the method claim limitations, the court agrees with DUSA that it has adduced sufficient unopposed evidence that the limitation is met. Luebbert, Biofrontera's CEO, admitted that the BF-RhodoLED is used to photodynamically treat a patient for dermatological conditions, *see* DUSA's Ex. 14, Luebbert Dep. Tr. (dkt # 269-14) at 182:4-12, including actinic keratosis (a pre-cancerous condition) and sun damage, *id.* at 179:22-179:25; acne, *id.* at 175:14-178:22; photodamaged skin; *id.* at 177:12-21; and cancer, *id.* at 177:22-178:22. Biofrontera also agreed in response to a request for admissions that the BF-RhodoLED outputs light that substantially matches the absorption spectrum of protoporphyrin IX. *See* DUSA's Ex. 16 (dkt # 269-16) at 23-24.

On the other hand, the court agrees with Biofrontera that DUSA's evidence does not establish actual use of the BF-RhodoLED for the treatment of warts. Although Biofrontera's manual and Form F-1 describe the BF-RhodoLED as indicated for warts, this is insufficient for its purpose. *See Fujitsu*, 620 F.3d at 1329 ("[T]he manuals and expert testing only show that the products are capable of infringing, they do not provide evidence of direct infringement."). Absent evidence of direct infringement, this limitation is not met.

ORDER

For the foregoing reasons, Biofrontera's motion for summary judgment as to DUSA's patent claims is DENIED. DUSA's cross motion is ALLOWED IN PART that the accused BF-RhodoLED meets claim limitations enumerated in the footnote, *infra*,[12] and is otherwise DENIED.

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[12]

- "photodynamically . . . treating a patient" (all asserted '289 patent claims);
- "illuminating the patient with an illuminator" (all asserted '289 patent claims);
- "wherein the spectral output of the illuminator substantially matches the absorption spectrum of protoporphyrin IX" ('289 patent claim 4);
- "comprising illuminating the patient to treat actinic keratosis" ('289 patent claim 7);
- "comprising illuminating the patient to treat acne" ('289 patent claim 8);

SO ORDERED.

/s/ Richard G. Stearns
UNITED STATES DISTRICT JUDGE

- "comprising illuminating the patient to treat photo damaged skin" ('289 patent claim 9);
- "comprising illuminating the patient to treat cancer" ('289 patent claim 10);
- "comprising illuminating the patient to treat a pre-cancerous condition" ('289 patent claim 15);
- "illuminator for treating a patient" (all asserted '991 patent claims);
- "plurality of light sources configurable in a spaced relationship to a patient to treat a dermatological condition" (all asserted '991 patent claims);
- "spectral output of the illuminator substantially matches an absorption spectrum of protoporphryin IX" ('991 patent claim 5);
- "generates light substantially entirely within the red region" ('991 patent claim 7);
- "non-fluorescent light sources" ('991 patent claim 9);
- "configured to illuminate the face of a patient" ('991 patent claim 10);and
- "wherein the light sources are configured and controlled to provide . . . output of at least one of blue light and red light to the patient to treat or diagnose a dermatological condition" ('992 patent claim 12).